UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/591,651	02/12/96	CLASSEN	J CLASSEN.1A

001444 HM22/0313
BRONDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON DC 20001-5303

EXAMINER	
BRUMBACK, B	
ART UNIT	**PAPER NUMBER**
1642	21

DATE MAILED: 03/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

DETAILED ACTION

Attachment to Advisory Action

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Item #3:

2. The Response to Advisory Action has been entered as Paper # 18. Pending claims are 5, 6, 8, 10, 11, 15, 16, 19, 26-30, 32-41, 43, 44, 46, 48-52, and 55-101. Claims 5, 6, 8, 10, 11, 15, 16, 19, 26-30, 32-41, 43, 44, 46, 48-52, and 55-101 stand rejected.

Item #4:

Request for Withdrawal of Finality:

3. Applicant's arguments presented in Paper # 18 have been fully considered but are not persuasive for the following reasons. Applicant continues to argue that the finality of the Office Action mailed 05/04/99 (Paper # 11) should be withdrawn because the examiner has introduced new grounds of rejection. The examiner maintains that no new grounds of rejection have been introduced for the reasons of record outlined in Paper # 16. In response to applicant's arguments regarding the statutory basis for the rejection and the reasoning advanced in the rejection, a review of the record clearly indicates that the statutory basis for the rejection has remained the

same throughout the prosecution and that the reasoning advanced for imposing the rejection has also remained the same. Any "new grounds of rejection" which applicant alleges have been made have simply been direct responses to arguments and issues raised by applicant when addressing the original rejection.

Applicant's allegation that the issue of extrapolation on data from bacterial immunogens to viral immunogens is different from the original issue, which was that the claims lack enablement for the wide range of immunogens is in error. Claims 2-17, 19, 21, and 23-55 were rejected in Paper # 7 as lacking enablement for the broad scope of the claims. Reasons provided for the rejection included a lack of enablement for the scope of the viral immunogens encompassed (see Paper # 7, and specifically page 4 and the paragraph bridging pages 4 and 5). As was pointed out in Paper # 16, the examiners comments regarding data extrapolation from bacterial to viral immunogens (Paper # 11, pages 3-4, paragraph 4a) were made in response to applicants arguments that data based on anthrax, plague, and DT (all bacterial antigens) is enabling for the broad scope of the claims, which includes a myriad of viral and other bacterial and nonbacterial antigens, as well as anthrax, plague and diphtheria (DT). Thus, no new issue was raised in addressing applicant's argument.

In response to applicant's arguments that the comments regarding extrapolation of data based on BCG to other (viral) immunogens again represents a new grounds of rejection, the examiner maintains that the grounds of rejection remains the same, *i.e.* lack of enablement for the broad scope of the immunogens encompassed in the claims. Once again, this is the same issue and

is not a new grounds of rejection, as is alleged by applicant. The comments made regarding the BCG data were made in direct response to applicant's argument advanced in Paper # 10 that data generated from immunization with BCG is enabling for the broad scope of the claims (see Paper # 10, page 21, third full paragraph).

Applicant alleges that a third new ground of rejection was made when applicant's arguments regarding extrapolation of data from mice to humans were addressed. This is simply not the case. The claims have been rejected based on a lack of enablement for the broad scope of the claims, which encompass treating a myriad of chronic immune mediated disorders in humans. This was addressed in the reasoning advanced in the original rejection (see Paper # 7, pages 2-4). In response to the rejection, applicant argued that mouse data presented in the disclosure is enabling for the full scope of the claims (see paper # 15, pages 15-16, 5.7, first five paragraphs). The examiner's comments regarding extrapolation of mouse data were made in direct response to applicant's argument. The issue and the ground of rejection, however, remained the same.

Finally, in response to applicant's allegation that the advisory action fails to address at all the request for withdrawal of finality, applicant is referred to page 2, paragraph 3 of the attachment to the advisory action, wherein it is specifically stated,

> "Applicant argues that the finality of the Office Action mailed 05/04/99 (Paper # 11) should be withdrawn because the examiner introduced new grounds of rejection. This is not found persuasive because the examiner finds no new grounds that were introduced in Paper # 11".

The remainder of paragraph 3 (pages 2-4) elucidates in detail the reasons for the finding that no new grounds of rejection had been introduced.

Prior art:

4. Applicant's comments regarding the Food, Drug and Cosmetic Act are noted; however, their relevance to the present application is not clear.

In response to applicant's argument regarding In re Gulak and In re Miller, the examiner maintains that their is no functional relationship between the label and the immunogen in the present case, as was found to exist in the measuring cup of In re Miller and the mathematical device of In re Gulak. The immunogen remains an immunogen in the absence of the label.

Applicant's comments regarding In re Lowry and the electromagnetic changes upon structures upon storage in memory are noted; however, once again their relevance to the present case is not understood.

Applicant's reasoning in alleging that the PTO has conceded the functionality of the labeling in the kit claims because claims drawn to a method have been allowed in U.S. patent 5,728,385 and because the present method claims have not been rejected over the prior art is not understood.

Definiteness:

5. Applicant's comments regarding the indefiniteness of an immunogen other than BCG are noted; however, this argument has been previously addressed (see Paper # 16, pages 6-7, paragraph 8) and no new argument has been presented herein. Once again, applicant's allegation the examiner's response to applicant's argument raises a new grounds of rejection is in error. No new ground of rejection was raised. The examiner simply responded to applicant's argument.

Description:

6. Applicant's arguments regarding statements instructing the PTO to consider canceled claims as presented on filing in the "transmittal letter, item 4" is noted; however, applicant has not pointed out where support for the newly recited material can be found in the referenced claims. Upon review of the canceled claims, it would appear that only some of the newly added limitations are supported by the canceled claims. Clarification is required.

Enablement:

7. Applicant's arguments regarding enablement for the full scope of the viral immunogens claimed have been previously addressed at length.

Applicant's comments regarding viral strains and method of travel through the blood (page 9, third paragraph) are noted; however, their relevance to the present case is not clear. Applicant's comments regarding HIV, CMV, and HSV immunogens are also noted; however, the

examiner maintains that no effective vaccines are known in the art for these viruses. The referenced articles could not be considered, as no copies of the articles or the abstracts were found with the response filed 02/12/96.

Lastly, applicant's arguments regarding maturation rates of mice and extrapolation of data to humans, has been addressed at length. Applicant is referred to Paper # 7, the paragraph bridging pages 5 and 6; to Paper # 11, the paragraph bridging pages 5 and 6; and to Paper # 16, page 3, second full paragraph, for review.

Applicant's statement regarding the rate of replication of viruses in humans and mice is noted; however, its relevance to the presently claimed invention prevention of chronic immune-mediated disorders, as is claimed herein, is not clear. Additionally, the examiner does not completely agree with applicant's statement that viruses replicate at the same rate in mice and humans. Many viruses, including HIV and human CMV, which were cited by applicant in the preceeding paragraph of the response (the paragraph bridging pages 9 and 10), are human pathogens which do not replicate in mice at all.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Paula Hutzell whose telephone number is (703) 308-4310. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014.

FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB
March 1, 2000

PAUL
SUPERVISORY PATENT EXAMINER